

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CAROL LEWIS,
Plaintiff,

v.

CIVIL ACTION NO.
15-13530-NMG

SYLVIA BURWELL,
Secretary of the United States
Department of Health and Human
Services,
Defendant.

**REPORT AND RECOMMENDATION RE:
DEFENDANT'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER
JURISDICTION AND FOR FAILURE TO STATE A CLAIM
(DOCKET ENTRY # 12)**

September 4, 2016

BOWLER, U.S.M.J.

Pending before this court is a motion to dismiss filed by defendant Sylvia Burwell, Secretary of the United States Department of Health and Human Services ("the Secretary"). (Docket Entry # 12). The Secretary moves to dismiss the complaint under Fed.R.Civ.P. 12(b)(1) ("Rule 12(b)(1)") for lack of subject matter jurisdiction and to dismiss Count VIII of the complaint under Fed.R.Civ.P. 12(b)(6) ("Rule 12(b)(6)") for failure to state a claim. (Docket Entry # 12). Plaintiff Carol Lewis ("plaintiff") opposes the motion. (Docket Entry ## 14, 30).

PROCEDURAL BACKGROUND

This action arises under Part B of the Medicare Act. (Docket Entry # 1, ¶ 21). Plaintiff filed a claim with the National Health Insurance Corporation ("NHIC"), a Medicare administrative contractor, for Medicare Part B coverage of expenses in connection with a continuous glucose monitor ("CGM") ("the Medicare coverage claim" or "the Medicare coverage proceeding"). (Docket Entry # 1, ¶ 85). NHIC denied the claim and plaintiff "appealed the denial through the Medicare administrative appeal process." (Docket Entry # 1, ¶¶ 85, 86).

In December 2014, plaintiff initiated a separate proceeding by filing a complaint with the Civil Remedies Division of the Departmental Appeals Board ("DAB"). The complaint requested review of a provision in NHIC article 33614 ("A33614"), which is a local coverage article or "LCA," that characterized CGM as "precautionary." The complaint also involved a related local coverage determination ("LCD") for glucose monitors designated L11530 ("L11530") ("the LCD claim" or "the LCD proceeding"). (Docket Entry # 35-1).¹ On September 11, 2015, an administrative law judge ("the DAB ALJ") determined that the LCD record "was not complete and adequate to support the validity of" L11530 under a reasonableness standard. (Docket Entry # 1, ¶¶ 97, 98) (Docket Entry # 35-1, p. 2). Accordingly, the DAB ALJ allowed

¹ The complaint in this case refers to the LCD proceeding and the above filing is therefore part of the Rule 12(b)(6) record.

the parties to engage in discovery which led to an April 29, 2016 decision by the DAB ALJ. (Docket Entry # 1, ¶¶ 9, 95) (Docket Entry # 35-1, p. 2). The matter is currently pending on appeal with the DAB. (Docket Entry # 36-2).

On October 8, 2015, plaintiff filed this action seeking review of the Medicare coverage decision issued on September 25, 2015. (Docket Entry # 1, ¶¶ 1, 79). The complaint states that this court has subject matter jurisdiction under 42 U.S.C. §§ 405(g) ("section 405(g)") and 1395ff(b); 28 U.S.C. § 1331 ("section 1331"); and 28 U.S.C. § 1361 ("section 1361"). (Docket Entry # 1, ¶ 15). Plaintiff requests an order "reversing [the] coverage denials and instructing the Secretary to pay the claims at issue in accordance with applicable law." (Docket Entry # 1, ¶ 14).

The complaint sets out eight counts against the Secretary. (Docket Entry # 1, pp. 16-20). Captioned as violations of 5 U.S.C. § 706, counts I through VII allege violations of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. More specifically, Count I requests that this court reverse the Secretary's decision that CGM is precautionary and excluded from coverage "because [the decision] is contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record" and "issue an order finding that the CGM is not precautionary and is reasonable and medically necessary, and

direct the Secretary to make appropriate payment for the device." (Docket Entry # 1, ¶ 109). Count II requests that this court reverse the Secretary's decision that CGM is not covered under section 40.2 of the Medicare National Coverage Determination Manual ("NCD 40.2") "because [the decision] is arbitrary, capricious, and unsupported by substantial evidence in the record" and "reverse . . . [the Secretary]'s decision and issue an order finding that the CGM is reasonable and medically necessary under NCD 40.2." (Docket Entry # 1, ¶¶ 111-112). Count III requests that this court set aside the Secretary's decision that CGM is not covered under NCD 40.2 based on the Secretary's alleged failure to follow the NCD "because [the decision] is contrary to law, arbitrary and capricious and without observance of procedure required by law." (Docket Entry # 1, ¶¶ 111-112). Count IV requests that this court reverse the Secretary's decision that CGM is not covered under LCD L27231 ("L27231") "because [the decision] is arbitrary, capricious, and unsupported by substantial evidence in the record" and "issue an order finding that the CGM is reasonable and medically necessary under LCD L11530." (Docket Entry # 1, ¶¶ 116-117). Count V requests that this court reverse the Secretary's decision that CGM is not covered under L11530 based on the Secretary's alleged failure to apply L11530 "because [the decision] is contrary to law, arbitrary and capricious and without observance of

procedure required by law" and "issue an order finding that the CGM is reasonable and medically necessary under LCD L11530 and directing . . . [the Secretary] to follow LCD L11530." (Docket Entry # 1, ¶¶ 119-120). Count VI requests that this court set aside the Secretary's decision to the extent that it deferred to the A33614 "because [the decision] is contrary to law, regulation and arbitrary and capricious, and without observance of procedure required by law." (Docket Entry # 1, ¶ 122). Count VII requests that this court set aside the Secretary's decision based on the Secretary's alleged failure to follow the statutory definition of DME² "because [the decision] is contrary to law, regulation, [the Secretary's] own manual provisions, is arbitrary and capricious, and without observance of procedure required by law." (Docket Entry # 1, ¶ 126). Count VIII requests that this court grant mandamus relief under section 1361. (Docket Entry # 1, ¶¶ 130-132).

The Secretary moves to dismiss counts I through VII of the complaint for lack of subject matter jurisdiction under Rule 12(b)(1) and, with respect to Count VIII, for failure to state a claim under Rule 12(b)(6). (Docket Entry # 13). Specifically, the Secretary seeks: (1) dismissal of counts IV, V, and VI because there is no final decision or agency action with respect to the LCD proceeding and the claims are therefore not ripe for

² The acronym DME refers to durable medical equipment.

review; (2) dismissal of counts I through VII because the APA does not provide judicial review of the claims; and (3) dismissal of Count VIII because plaintiff is not entitled to mandamus relief. (Docket Entry ## 13, 20).

STANDARDS OF REVIEW

With respect to the Rule 12(b)(1) motion, the court must credit the plaintiff's well-pled factual allegations and draw all reasonable inferences in the plaintiff's favor. See Merlonghi v. U.S., 620 F.3d 50, 54 (1st Cir. 2010) (citing Valentin v. Hospital Bella Vista, 254 F.3d 358, 363 (1st Cir. 2001)); accord Sánchez ex rel. D.R.-S. v. U.S., 671 F.3d 86, 92 (1st Cir. 2012) ("credit[ing] the plaintiff's well-pled factual allegations and draw[ing] all reasonable inferences in the plaintiff's favor" under Rule 12(b)(1)). "The district court may also 'consider whatever evidence has been submitted, such as the depositions and exhibits submitted.'" Merlonghi v. U.S., 620 F.3d at 54 (quoting Aversa v. U.S., 99 F.3d 1200, 1210 (1st Cir. 1996)). Accordingly, this court may consider the evidence of a scheduling order, a notice of appeal, an acceptance of the appeal and the DAB ALJ's decision. (Docket Entry ## 20-1, 35-1, 36-1, 36-2).

Rule 12(b)(1) is "the proper vehicle for challenging a court's subject matter jurisdiction." Valentin v. Hospital Bella Vista, 254 F.3d at 362. Because federal courts are courts

of limited jurisdiction, federal jurisdiction is never presumed. Fafel v. Dipaola, 399 F.3d 403, 410 (1st Cir. 2005). When a defendant challenges subject matter jurisdiction, the plaintiff bears the burden of proving jurisdiction. Johansen v. U.S., 506 F.3d 65, 68 (1st Cir. 2007). Dismissal is appropriate when the facts alleged in the complaint, taken as true, "do not support a finding of federal subject matter jurisdiction." Fothergill v. U.S., 566 F.3d 248, 251 (1st Cir. 2009).

With respect to the standard of review for a Rule 12(b)(6) motion, the complaint must include factual allegations that when taken as true demonstrate a plausible claim for relief even if actual proof of the facts is improbable. Bell Atlantic v. Twombly, 550 U.S. 544, 555-558 (2007). Thus, while "not equivalent to a probability requirement, the plausibility standard asks for more than a sheer possibility that a defendant has acted unlawfully." Boroian v. Mueller, 616 F.3d 60, 65 (1st Cir. 2010) (internal quotation marks omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint . . . has not shown that the pleader is entitled to relief." Feliciano-Hernandez v. Pereira-Castillo, 663 F.3d 527, 533 (1st Cir. 2011) (internal quotation marks and citations omitted). Discarding legal conclusions and taking the facts in the governing complaint as true and read in a plaintiff's favor "even if

seemingly incredible," Bruns v. Mayhew, 750 F.3d 61, 71 (1st Cir. 2014), the complaint "must state a plausible, but not a merely conceivable, case for relief." Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011); see Sepúlveda-Villarini v. Department of Education, 628 F.3d 25, 29 (1st Cir. 2010).

In evaluating a Rule 12(b)(6) motion, the court may consider a limited category of documents outside the complaint without converting the motion into one for summary judgment. Such documents include public records, facts subject to judicial notice and documents sufficiently referred to in the complaint. See Butler v. Balolia, 736 F.3d 609, 611 (1st Cir. 2013) (supplementing facts in complaint "by examining 'documents incorporated by reference into the complaint, matters of public record, and facts susceptible to judicial notice'"); Freeman v. Town of Hudson, 714 F.3d 29, 36 (1st Cir. 2013) (court may consider "'official public records; documents central to plaintiffs' claim; and documents sufficiently referred to in the complaint'") (ellipses and internal brackets omitted).

FACTUAL BACKGROUND

A national coverage determination ("NCD") is a determination regarding coverage that exists nationally for Medicare beneficiaries. (Docket Entry # 1, ¶ 6). NCD 40.2 provides coverage for home blood glucose monitors for Medicare

beneficiaries who are diabetics. (Docket Entry # 1, ¶ 6). In 2008, NHIC issued the local coverage determination L11530 "indicating that blood glucose monitors and related accessories and supplies" are covered by Medicare when: "(1) a patient had diabetes which . . . a physician [treated]; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use." (Docket Entry # 1, ¶ 7). L11530 "did not indicate that the CGM was not covered," but NHIC issued the aforementioned article, A33614, "stating that NHIC considers CGM . . . 'precautionary.'" (Docket Entry # 1, ¶ 8).

Plaintiff is a Medicare beneficiary who resides in Chatham, Massachusetts. (Docket Entry # 1, ¶ 17). She has been a Medicare beneficiary since at least January 1, 2013 and "has had Type 1 diabetes for 30 years." (Docket Entry # 1, ¶¶ 18, 80). Despite conscientiously "following nutritional instructions, regularly exercising, performing frequent . . . [testing six or more times daily], and following a comprehensive insulin administration regimen for her diabetes, her glucose levels still remain uncontrolled, i.e. 'brittle.'" (Docket Entry # 1, ¶¶ 2, 81). Plaintiff "also suffers from hypoglycemia and hypoglycemic unawareness." (Docket Entry # 1, ¶ 81). Prior to becoming eligible for Medicare, plaintiff's healthcare provider prescribed plaintiff a CGM that checked "her glucose

approximately 288 times a day" and alerted her to hypoglycemic events. (Docket Entry # 1, ¶¶ 4, 82). Plaintiff's healthcare provider stated "that CGM was and is reasonable and medically necessary" for plaintiff. (Docket Entry # 1, ¶ 83). Plaintiff experienced "a 'vast' clinical improvement of her blood glucose level control" when she used the CGM prescribed by her previous healthcare provider. (Docket Entry # 1, ¶ 84).

Plaintiff initially "filed a claim" with NHIC to cover the costs for CGM and related supplies. (Docket Entry # 1, ¶ 85). As noted previously, NHIC denied the claim and plaintiff "appealed the denial through the Medicare administrative process." (Docket Entry # 1, ¶¶ 85, 86).

On July 7, 2013, plaintiff requested a hearing before an administrative law judge ("the ALJ"). (Docket Entry # 1, ¶ 87). On October 30, 2013, plaintiff received a hearing before the ALJ. (Docket Entry # 1, ¶ 88). During the hearing, plaintiff's healthcare provider testified that CGM "was not precautionary but was medically necessary and essential for [plaintiff]." (Docket Entry # 1, ¶ 89). Plaintiff's healthcare provider further explained that plaintiff's "medical need for CGM is extreme" and that "CGM prevents hypoglycemic and hyperglycemic events and premature death." (Docket Entry # 1, ¶ 90-91).

On February 6, 2014, the ALJ rendered a decision "that CMG is not covered by Medicare." (Docket Entry # 1, ¶ 93). In

March 2014, plaintiff filed an appeal with the Medicare Appeals Council ("AC") requesting review of the ALJ's decision. (Docket Entry # 1, ¶¶ 11, 94); see 42 U.S.C. § 1395ff(d)(2)(A).³

In December 2014, plaintiff separately filed the LCD claim challenging the provision in the aforementioned NHIC article (A33614) that CGM was precautionary. (Docket Entry # 1, ¶¶ 9, 95). In particular, plaintiff "challenged the constructive LCD that arises from the language in LCA A33614, which provides that . . . [CGMs] are not covered by the Medicare DME benefit because CGM[s] [are] 'precautionary.'" (Docket Entry # 35-1, p. 2). "In response to the challenge, NHIC did not produce a single article or [an] opinion of a medical expert to support its assertion that CGM was precautionary." (Docket Entry # 1, ¶ 96). On September 11, 2015, the DAB ALJ issued a decision and found that the A33614's provision asserting that CGM was "precautionary was not supported by the LCD Record" and set a schedule for the parties to engage in discovery. (Docket Entry # 35-1, p. 3) (Docket Entry # 1, ¶ 97) (Docket Entry # 20-1).

Meanwhile, having not obtained a decision by the AC, plaintiff filed a "request for escalation to Federal district

³ The AC is actually a "division of the DAB" and is "referred to as the 'MAC' in regulatory provisions." American Hospital Association v. Burwell, 76 F.Supp.3d 43, 46 (D.D.C. 2014), rev'd and remanded on other grounds, 812 F.3d 183 (D.C.Cir. 2016). The Medicare statute refers to the DAB, as opposed to its division, the AC. See, e.g., 42 U.S.C. § 1395ff(d)(2)(A).

court," see 42 C.F.R. § 405.1132, in the Medicare coverage proceeding on September 14, 2015. (Docket Entry # 1, ¶ 99). On September 25, 2015, the AC rendered a decision that affirmed the ALJ's denial of coverage to plaintiff in the Medicare coverage proceeding "although [the AC] modified the basis of denial." (Docket Entry # 1, ¶¶ 12, 101). The AC found that "CGM is simply precautionary, does not serve a medical function, and therefore is not covered under the DME Medicare benefit." (Docket Entry # 1, ¶ 102). Plaintiff filed this action in October 2015 within the 60-day time period. See 42 C.F.R. § 1130.

"On September 30, 2015, NHIC retired LCD L11530 and LCA 33614 and reissued substantively the same documents designated LCD L33822 and LCA A52464." (Docket Entry # 35-1, p. 3). On December 1, 2015, NHIC filed copies of LCD L33822 ("L33822") and LCA A52464 ("A52464"), which the DAB ALJ construed as "substantially the same" as L11530 and A33614. (Docket Entry # 35-1, p. 3).

On April 29, 2016, the DAB ALJ issued the decision in which he ruled that the "provision of the constructive LCD contained in LCD L11530/L33822 and LCA33614/A52464 that states '[c]ontinuous glucose monitors (A9276-A9278) are considered precautionary and therefore not covered under the DME . . . benefit' is not valid under the reasonableness standard."

(Docket # 35-1, p. 22). The decision also determined that CGM met "the statutory definition of DME." (Docket Entry # 35-1, p. 20). On May 27, 2016, DAB received the notice of appeal filed by CMS regarding the April 29, 2016 decision and deemed the appeal "timely filed" and "otherwise an acceptable appeal." (Docket Entry # 36-2).

DISCUSSION

I. Rule 12(b)(1) Motion to Dismiss

A. LCD Challenge

The Secretary moves to dismiss counts IV, V and VI because there is no final agency action in the LCD proceeding given the pendency of the appeal and the claims are therefore not ripe for review. The Secretary similarly submits plaintiff has not exhausted her administrative remedies. The argument assumes that these counts are attacks on the LCD proceeding as opposed to challenges to the Secretary's September 25, 2015 Medicare coverage decision. In a sur-reply brief, plaintiff asserts she "is not seeking review of the local coverage determination." (Docket Entry # 30, p. 2). At the outset, therefore, it is necessary to address the contours of the claims as pled in counts IV, V and VI. The complaint captions all three counts as a violation of the APA, 5 U.S.C. § 706.

Counts IV and V attack the Secretary's decision that the CGM is precautionary and request "an order finding that the CGM

is reasonable and medically necessary under LCD L11530."⁴ (Docket Entry # 1, ¶¶ 115-120). Count VI attacks the Secretary's decision insofar as it gave deference to A33614, "which is not an LCD," and the Secretary's refusal to give deference to L11530. (Docket Entry # 1, ¶¶ 121-124). The complaint also states, "This is an action for judicial review of the final administrative decision of the Secretary" issued on September 25, 2015, i.e., the appeal of the Medicare coverage claim, and counts IV, V and VI incorporate by reference this language as well as all previous paragraphs in the complaint (Docket Entry # 1, ¶¶ 79, 115, 118, 121). The first paragraph of the complaint likewise states this is an action under the Medicare Act and the APA seeking "judicial review of a final decision" of the Secretary "*denying Medicare payment* for claims relating to a [CGM]." (Docket Entry # 1, ¶ 1) (emphasis added).

In addition, the complaint outlines the appeal process of a Medicare coverage claim and the separate process for an appeal of a challenge to an LCD. The complaint further identifies the administrative proceedings plaintiff herself employed with respect to the Medicare coverage claim (including the September 25, 2015 decision denying the claim) and the separate challenge

⁴ The caption of Count IV alleges a violation of the APA on the basis that "CGM is not non-covered under LCD L27231." (Docket Entry # 1, p. 17). The complaint does not describe the substance of LCD L27231. The body of the count refers only to L11530.

to L11530/A33614. The only "decision" identified in the complaint with respect to the latter LCD/article challenge is the September 11, 2015 decision.

As noted above, in the sur-reply plaintiff represents she "is not seeking review of the local coverage determination." (Docket Entry # 30). Rather, she is "seeking review of *her individual claim* and is asserting the denial of her claim is inconsistent with the LCD and a National Coverage Determination," i.e., NCD 40.2. (Docket Entry # 30) (emphasis added).

A complaint is construed and interpreted in accordance with its plain language and structure. See Cortes-Rivera v. Department of Corrections and Rehabilitation of Commonwealth of Puerto Rico, 626 F.3d 21, 28 (1st Cir. 2010) (examining "plain language" of complaint and its structure to determine if it raised a claim); see also Narragansett Jewelry Co., Inc. v. St. Paul Fire And Marine Ins. Co., 555 F.3d 38, 41 (1st Cir. 2009); Coffin v. Bowater Inc., 501 F.3d 80, 96 (1st Cir. 2007). The plain language of Count VI challenges the application of A33614 as improperly designating CGM precautionary, when, in fact, CMG "is reasonable and medically necessary" under L11530 and therefore subject to coverage under the Medicare Act. (Docket Entry # 1, ¶¶ 121-124). The count also criticizes the Secretary's decision giving deference to A33614 and not

"giv[ing] deference to the LCD." (Docket Entry # 1, ¶¶ 122, 123). The September 11, 2015 decision in the LCD proceeding by the DAB ALJ directed the parties to engage in discovery and the complaint describes that decision as finding that the record did not support A33614's designation of CGM as precautionary. (Docket Entry # 1, ¶ 97). As stated in the complaint, it was the September 25, 2015 decision in the Medicare coverage proceeding that "found that the CGM is simply precautionary." (Docket Entry # 1, ¶ 102).

The plain language in counts IV and V also ties the alleged violations to the September 25, 2015 decision in the Medicare coverage claim as opposed to the September 11, 2015 decision in the LCD proceeding. First, both counts seek "to reverse the Secretary's decision and issue an order that the CGM is reasonable and medically necessary under L11530." (Docket Entry # 1, ¶ 117, 120). Second, the September 25, 2015 decision denied plaintiff Medicare coverage and payment for CGM whereas the September 11, 2015 decision ordered discovery in the LCD proceeding in lieu of declaring the constructive LCD in A33614 valid. See 42 C.F.R. § 426.430. More specifically, the September 25, 2015 decision found that CMG was precautionary and therefore "not covered under the DME Medicare benefit." (Docket Entry # 1, ¶ 102).

In addition, the September 11, 2015 decision, which "found

that the LCD record NHIC had submitted was not complete and adequate to support the validity of the constructive LCD under the reasonableness standard" (Docket Entry # 35-1, p. 3), was *favorable* to plaintiff. It is illogical that the counts in the complaint alleging violations of the APA would challenge a decision rendered in plaintiff's favor. The plaintiff-favorable nature of the decision is apparent not only because of the complaint's description of the decision (Docket Entry # 1, ¶¶ 97, 98) but because of the relevant regulations confining the parameters of a DAB ALJ's review of an LCD challenge. See 42 C.F.R. §§ 426.300-426.490.

Addressing the latter, a DAB ALJ's initial evaluation under a reasonableness standard is "to determine whether the LCD record is complete and adequate to support the *validity* of the LCD." 42 C.F.R. § 426.430(c) (emphasis added). If the DAB ALJ decides that the LCD record is adequate to support the validity of the LCD, then the review process "*ends*." 42 C.F.R. § 426.430(c)(2) (emphasis added). If not, then the DAB ALJ "permits discovery" and evaluates the LCD under the reasonableness standard. 42 C.F.R. § 426.430(c)(3); see 42 U.S.C. § 1395ff(f)(2)(A). To state the obvious, it is more favorable to plaintiff to obtain a decision for the parties to engage in discovery than to obtain a decision ending the review process on the basis that the record adequately supports the

validity of the constructive LCD in A33614 that CGM is precautionary.

To explain the administrative process in greater detail, once the DAB ALJ issues a decision, 42 C.F.R. § 426.465 outlines the appeal rights of an aggrieved party,⁵ a contractor and CMS. An aggrieved party such as plaintiff may appeal any part of the DAB ALJ's decision that "[s]tates that a provision of an LCD is *valid* under the reasonableness standard" or dismisses the complaint. 42 C.F.R. § 426.465 (emphasis added). The record before this court does not contain such a decision and the most recent decision by the DAB ALJ found the provision in the constructive LCD in A33614 that CGM is precautionary was invalid under the reasonableness standard. (Docket Entry # 35-1). NHIC or CMS, in turn, may file an appeal with the DAB of any part of a DAB ALJ's "decision that states that a provision" of an LCD is unreasonable. 42 C.F.R. § 426.465. Here, CMS exercised that right by filing an appeal of the DAB ALJ's April 29, 2016 decision with the DAB, which accepted the appeal in late May 2016. It is the decision by the DAB that "constitutes a final agency action and is subject to judicial review." 42 U.S.C. §

⁵ An aggrieved party is defined as an individual entitled to benefits under Medicare Part A or enrolled in Medicare Part B who is in need of coverage. See 42 C.F.R. § 426.110; 42 U.S.C. § 1395ff(f)(2).

1395ff(f)(2). Once the DAB issues the final decision, only an aggrieved party may seek judicial review in court. See 42 U.S.C. § 1395ff(f)(5); 42 C.F.R. § 426.490. "Neither the contractor nor CMS may appeal a Board decision." 42 C.F.R. § 426.490.

In a Medicare coverage proceeding, the decision by the AC is the final decision and "[a] party may file an action in a Federal district court within 60" days after receiving notice of the AC's decision. 42 C.F.R. § 405.1130. The Secretary is the proper party in such an action. 42 C.F.R. § 405.1136(d).

In sum, the plain language of the complaint leads to a conclusion that counts IV, V and VI set out causes of action under the APA attacking, on various grounds, the September 25, 2015 decision in the Medicare coverage proceeding. The counts do not attack the plaintiff-favorable September 11, 2015 decision in the LCD proceeding.⁶ Accordingly, consistent with plaintiff's representation in the sur-reply, counts IV, V and VI are challenges to the decision of the Secretary in the Medicare coverage proceeding.⁷ The Secretary's motion to dismiss counts

⁶ To state the obvious, the plain language of the complaint does not attack the April 29, 2016 decision in the LCD proceeding because of a number of reasons, one of which being that the decision was not issued when the complaint was filed.

⁷ To the extent plaintiff wishes to attack a decision by the Secretary in the LCD proceeding, it is therefore incumbent upon plaintiff to seek leave to amend the complaint.

IV, V and VI because the Secretary has not issued a final agency action and plaintiff has not exhausted the administrative review process regarding the challenge to the LCDs and LCAs is therefore moot. Stated otherwise, the Secretary's argument does not address the challenge to the Medicare coverage claim and it is that claim that is the subject of the APA causes of action in counts IV, V and VI under the plain language in the complaint.

B. Medicare Coverage Challenge

The Secretary next moves to dismiss counts I through VII under Rule 12(b)(1) for lack of subject matter jurisdiction because the APA does not provide judicial review of the claims in these counts, all of which assert violations of the APA.⁸ (Docket Entry ## 13, 20). According to the Secretary, the APA applies when "there is no other adequate remedy" (Docket Entry # 13) (quoting 5 U.S.C. § 704) and the Medicare Act contains an adequate remedy, i.e., 42 U.S.C. § 1395ff(b) ("section 1395ff(b)"). The Secretary reasons that section 1395ff(b) adopts sections 405(g) and (h) "as conferring jurisdiction for review of Medicare decisions." (Docket Entry # 13, p. 12). The Secretary also asserts that the review provided under the

⁸ The Secretary does not seek to dismiss these counts under Rule 12(b)(6). Although the motion itself requests dismissal under Rules 12(b)(1) and 12(b)(6) without identifying the specific counts, the supporting memorandum clarifies that the Secretary "requests that this Court dismiss the Complaint for lack of jurisdiction and, as to Count VIII, for failure to state a claim upon which relief can be granted." (Docket Entry # 13, p. 1).

Medicare Act is the "substantial evidence" standard in section 405(g). (Docket Entry # 13) (citing Rodriguez v. Secretary of Health and Human Services, 647 F.2d 219, 222 (1st Cir. 1981), which quotes "substantial evidence" provision in section 405(g)).

Plaintiff disagrees that the "substantial evidence" standard in section 405(g) applies. She additionally points out that the APA also uses a "substantial evidence" standard. (Docket Entry # 14, p. 14) (citing 5 U.S.C. § 706(2)(E)). Notably, plaintiff argues that the Secretary confuses the jurisdictional basis for review, i.e., section 405(g), with the standard of review, i.e., the APA's arbitrary and capricious, not supported by substantial evidence and otherwise contrary to law standard in 5 U.S.C. § 706. (Docket Entry # 30).

At the outset, it is worth recognizing that, with the exception of Count VIII for mandamus relief, all of the counts in the complaint set out causes of action under the APA. In fact, the caption in each of these counts reads in bold type, "Violation of APA under 5 U.S.C. § 706" and the body of the counts includes the requisite APA standard for liability, namely, "arbitrary and capricious" and/or "unsupported by substantial evidence," 5 U.S.C. § 706(2). (Docket Entry # 1). The only reasonable interpretation of this plain language, see Cortes-Rivera v. Department of Corrections and Rehabilitation of

Commonwealth of Puerto Rico, 626 F.3d at 28, is that counts I through VII set out causes of action under the APA. Thus, the complaint disclaims any reliance on the “substantial evidence” standard of review articulated in section 405(g).

Section 405(h), incorporated into the Medicare Act under section 1395ii, “makes the judicial review procedures under that statute the exclusive mechanism for litigating claims that arise under the Medicare Act.” Maine Department of Health and Human Services v. United States Department of Health and Human Services, 2015 WL 4872376, at *7 (D.Me. Aug. 13, 2015); see Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 9 (2000) (“[s]ection 1395ii makes § 405(h) applicable to the Medicare Act ‘to the same extent as’ it applies to the Social Security Act”). “The third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, *provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all ‘claim[s] arising under’ the Medicare Act.*” Heckler v. Ringer, 466 U.S. 602, 614-15 (1984) (citing Weinberger v. Salfi, 422 U.S. 749, 760-761 (1975)) (emphasis added).

Thus, with respect to subject matter jurisdiction, federal question jurisdiction under section 1331 does not provide a jurisdictional basis for this action and the complaint’s

reliance on it is misguided.⁹ See 42 U.S.C. §§ 405(h), 1395ii; Puerto Rican Association of Physical Medicine and Rehabilitation, Inc. v. U.S., 521 F.3d 46, 48 (1st Cir. 2008) (under section "405(h), which in terms relates to the Social Security program but is incorporated mutatis mutandis into the Medicare Act, id. § 1395ii, neither federal question nor federal defendant jurisdiction is available for suits 'to recover on any claim arising under' the Act"). Likewise, "the APA does not provide subject matter jurisdiction" over a claim arising under the Medicare Act. Maine Department of Health and Human Services v. United States Department of Health and Human Services, 2015 WL 4872376, at *7; see Califano v. Sanders, 430 U.S. at 107 (APA "does not afford an implied grant of subject-matter jurisdiction permitting federal judicial review of agency action"); Town of Portsmouth, R.I. v. Lewis, 813 F.3d 54, 63 (1st Cir. 2016) (even when "APA applies, . . . it does not confer jurisdiction"). The APA is neither an independent source nor a grant of subject matter jurisdiction.¹⁰ See Conservation Law Foundation, Inc. v.

⁹ The complaint does not raise a constitutional challenge, see Califano v. Sanders, 430 U.S. 99, 109 (1977) (recognizing limited exception for colorable constitutional claims under certain circumstances"); Matos v. Secretary of Health, Education and Welfare, 581 F.2d 282, 286 (1st Cir. 1978), or otherwise provide a basis to confer federal question jurisdiction, see American Chiropractic Association, Inc. v. Leavitt, 431 F.3d 812, 816 (D.C.Cir. 2005).

¹⁰ Wisely, therefore, the complaint does not cite the APA in the jurisdictional paragraph. (Docket Entry # 1, ¶ 15).

Busey, 79 F.3d 1250, 1261 (1st Cir. 1996) ("[w]hile the APA does not provide an independent source of subject matter jurisdiction, it does provide a federal right of action where subject matter jurisdiction exists under 28 U.S.C. § 1331"); accord Your Home Visiting Nurse Services, Inc. v. Shalala, 525 U.S. 449, 457-458 (1999) ("judicial-review provision of [APA], 5 U.S.C. § 706[,] . . . is not an independent grant of subject-matter jurisdiction"). In short, "federal question jurisdiction and the APA are not alternative basis for judicial review of claims arising under the Medicare Act." American Orthotic & Prosthetic Association, Inc. V. Sebelius, 62 F.Supp.3d 114, 122 (D.D.C. 2014) (paraphrasing Heckler v. Ringer, 466 U.S. at 620-622, in parenthetical). Rather, section 405(g) provides the applicable basis for subject matter jurisdiction.

The complaint, however, undeniably asserts section 405(g) as one of the bases of subject matter jurisdiction. (Docket Entry # 1, ¶ 15). Plaintiff also correctly maintains that subject matter jurisdiction differs from the standard of review. Indeed, "[t]he Supreme Court has stated that '[i]t is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the courts' statutory or constitutional power to adjudicate the case.'" United States v. Lahey Clinic Hospital, Inc., 399 F.3d 1, 15 (1st Cir. 2005) (quoting Verizon

Maryland, Inc. v. Pub. Serv. Comm. of Maryland, 535 U.S. 635, 642-643 (2002)). Procedurally, the Secretary attacks the APA counts solely on the basis of lack of subject matter jurisdiction under Rule 12(b)(1).¹¹ The Secretary's additional argument that the standard of review is supplied by the "substantial evidence" standard in section 405(g) as opposed to the arbitrary and capricious standard in the APA is a challenge to the validity of the APA causes of action as opposed to the subject matter jurisdiction of this court under Rule 12(b)(1). See id. (absence of "valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction"). As such, it is properly raised in a memorandum to affirm the Secretary's decision under section 405(g), which remains available for the Secretary to pursue. See 42 U.S.C. § 405(g). Rule 12(b)(1), however, does not provide a basis to address the correctness of the causes of action under APA. Accordingly, this court declines to address the merits of the APA causes of action under Rule 12(b)(1).

II. Rule 12(b)(6) Motion to Dismiss (Mandamus Relief)

As a final matter, the Secretary moves to dismiss Count VIII under Rule 12(b)(6). Count VIII is a claim for mandamus relief under section 1361 with respect to the Medicare coverage claim to compel the Secretary to comply with a statutory

¹¹ See footnote eight.

requirement in 42 U.S.C. § 1395ff(d)(1)(A) for the ALJ to “conduct and conclude a hearing on a decision of a qualified independent contractor” (“QIC”)¹² and issue “a decision on such [a] hearing” by the end of a “90-day period beginning on the date a request for hearing has been timely filed.” (Docket Entry # 1, ¶ 130) (quoting 42 U.S.C. § 1395ff(d)(1)(A)). Count VIII seeks additional mandamus relief to compel the AC to comply with a similar statutory deadline in 42 U.S.C. § 1395ff(d)(2)(A). (Docket Entry # 1, ¶ 131). The Secretary argues that the claim is moot because both the ALJ and the AC “issued decisions in [plaintiff’s] case” thus rendering “the agency decision final.” (Docket Entry # 20).

In the case at bar, plaintiff filed a claim for CGM, which NHIC denied, and thereafter “appealed the denial through the Medicare administrative appeal process,” i.e., she appealed a QIC denial. (Docket Entry # 1, ¶¶ 47, 85, 86). She requested a hearing before the ALJ on July 7, 2013. (Docket Entry # 1, ¶ 87). The ALJ did not issue a decision until February 6, 2014, well after the 90-day time period. (Docket Entry # 1, ¶ 93). Plaintiff filed the appeal in March 2014 requesting review of the ALJ’s decision. (Docket Entry # 1, ¶ 94). The AC issued

¹² “A Qualified Independent Contractor is an entity that contracts with the Secretary to decide requests for reconsideration.” Popkin v. Burwell, 2016 WL 1170939, at *1 (D.D.C. Mar. 24, 2016) (citing 42 C.F.R. § 405.902).

its decision on September 25, 2015, also well after the 90-day time period. (Docket Entry # 1, ¶¶ 79, 101).

With respect to an individual Medicare coverage claim, the statute imposes deadlines for the ALJ and the AC to render decisions. Specifically, the ALJ "shall conduct and conclude a hearing" and render a decision by "the end of the 90-day period beginning on the date a request for review has been timely filed." 42 U.S.C. § 1395ff(d)(1); see 42 U.S.C. 1395ff(d)(3); 42 C.F.R. § 405.1016(a). If the ALJ fails to issue a decision by the end of this 90-day period, the requesting party may request review by the AC and thereby escalate the matter to the AC. See 42 U.S.C. §§ 1395ff(d)(1), 1395ff(d)(3); 42 C.F.R. §§ 405.1016(a), 405.1104. The AC also has 90 days to issue a decision after receipt of a request for review or, in the case of an escalated review, 180 days after receipt of the request for escalation. See 42 U.S.C. §§ 1395ff(d)(2), 1395ff(d)(3); 42 C.F.R. § 405.1100. If the AC fails to adhere to the required time period, the plaintiff may seek judicial review of her Medicare coverage claim in federal court. See 42 U.S.C. § 1395ff(d)(3); 42 C.F.R. §§ 405.1100, 405.1136.

In order for a court to issue a writ of mandamus, a party must demonstrate "that he has exhausted all other avenues of relief and [that] the defendant owes him a clear, nondiscretionary duty." Heckler v. Ringer, 466 U.S. at 616.

Mandamus relief "is available only under exceptional circumstances of clear illegality." Cervoni v. Secretary of Health, Education & Welfare, 581 F.2d 1010, 1019 (1st Cir. 1978); In re Request from United Kingdom Pursuant to Treaty Between Govt. of U.S. and Govt. of United Kingdom on Mutual Assistance in Criminal Matters in the Matter of Dolours Price, 685 F.3d 1, 14 (1st Cir. 2012) ("Price") (mandamus is "an extraordinary writ reserved for special situations"). Among the "ordinary preconditions" for mandamus relief "are that the agency or official have acted (or failed to act) in disregard of a clear legal duty and that there be no adequate conventional means for review." Price, 685 F.3d at 14.

Mandamus relief is typically moot when the agency has already completed the necessary action. See Randall Wolcott v. Sebelius, 635 F.3d 757, 774 (5th Cir. 2010) (finding mandamus claim regarding removal from prepayment review moot because defendants had been removed from review). "[A] case is moot when the court cannot give any 'effectual relief' to the potentially prevailing party." Horizon Bank & Trust Co. v. Massachusetts, 391 F.3d 48, 53 (1st Cir. 2004); see Gebre v. Rice, 462 F.Supp.2d 186, 188 (D.Mass. 2006); see also Town of Portsmouth, R.I. v. Lewis, 813 F.3d 54, 58 (1st Cir. 2016).

Here, mandamus relief is moot with respect to the individual Medicare coverage claim because the ALJ issued a

decision and the AC issued a final decision on September 25, 2015. Plaintiff then filed this action within the required 60-day time period. See 42 C.F.R. § 405.1130. This court cannot provide effectual relief to compel the ALJ to render a decision and for the AC thereafter to render a decision on the appeal with respect to plaintiff because the ALJ and the AC have already acted by issuing decisions, albeit belatedly. Hence, compelling the ALJ or the AC to render a decision for plaintiff in a timely manner is moot. In addition, because the individual Medicare coverage claim is pending in this action, plaintiff has an adequate remedy at least with respect to reviewing the AC and the ALJ's actual decisions thereby rendering mandamus relief inappropriate. See Gebre v. Rice, 462 F.Supp.2d at 188.

Plaintiff points out, however, that she has a recurring need for CGM supplies and that she, along with other Medicare beneficiaries in need of CGM, will continue to be subjected to the Secretary's failure to abide by the statutory obligations of rendering timely decisions. (Docket Entry ## 14, 30). First, plaintiff lacks standing to raise the claims of other Medicare beneficiaries. Second, there is no reasonable expectation that the conduct of not rendering timely decisions will be repeated, see Town of Portsmouth, R.I. v. Lewis, 813 F.3d at 59, with respect to plaintiff's individual Medicare coverage claim because this action is pending before the court for

adjudication. Plaintiff exhausted the appeals process, obtained a final decision by the AC and timely filed this action against the Secretary within the 60-day time period. See 42 C.F.R. § 405.1130. Thus, unlike the inadequacy of escalation for the hospitals seeking reimbursement payments in American Hospital Association v. Burwell, 812 F.3d 183, 192 (D.C.Cir. 2016), a case cited by plaintiff, plaintiff will obtain an adjudication of the overriding CGM issues in this case. It is also unlikely she will need to obtain an escalation in future Medicare coverage claims or be subject to delays before the ALJ and the AC because this case should resolve the merits of her entitlement to Medicare coverage for CGM as a DME Medicare benefit. Because the AC's decision is final, 42 C.F.R. § 405.1130, and the Secretary's decision is presently subject to review in this court, there is no remaining agency action left for this court to compel by a writ of mandamus. See Randall Wolcott, 635 F.3d at 774. Accordingly, Count VIII is subject to dismissal.

CONCLUSION

In accordance with the foregoing discussion, this court **RECOMMENDS**¹³ that the Secretary's motion to dismiss the complaint

¹³ Any objections to this Report and Recommendation must be filed with the Clerk of Court within 14 days of receipt of the Report and Recommendation to which objection is made and the basis for any such objection. See Rule 72(b), Fed. R. Civ. P.

(Docket Entry # 12) be **DENIED** as to lack of subject matter jurisdiction under Rule 12(b)(1) and **ALLOWED** as to Count VIII for failure to state a claim under Rule 12(b)(6).

/s/ Marianne B. Bowler

MARIANNE B. BOWLER

United States Magistrate Judge

Failure to file objections within the specified time waives the right to appeal the order.